Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program											Date: February 2015	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0602115HP *I Applied Biomedical Technology*							
COST ($ in Millions)	**Prior Years**	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**Cost To Complete**	**Total Cost**
Total Program Element	118.565	59.968	73.201	58.251	-	58.251	68.797	80.447	83.982	89.223	Continuing	Continuing
200A: *Congressional Special Interests*	55.883	15.000	25.303	-	-	-	-	-	-	-	-	-
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	-	-	-	3.150	-	3.150	3.157	2.552	1.949	1.949	Continuing	Continuing
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	3.377	3.535	2.968	-	-	-	-	-	-	-	Continuing	Continuing
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	-	-	-	1.728	-	1.728	1.757	1.987	2.025	2.066	Continuing	Continuing
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	-	-	-	1.728	-	1.728	1.758	1.988	2.026	2.066	Continuing	Continuing
372A: *GDF Applied Biomedical Technology*	59.305	33.023	37.755	43.579	-	43.579	53.913	64.631	68.517	73.488	Continuing	Continuing
447A: *Military HIV Research Program (Army)*	0.000	8.410	7.175	8.066	-	8.066	8.212	9.289	9.465	9.654	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Guidance for Development of the Force - Applied Biomedical Technology: This applied research funding is to refine concepts and ideas into potential solutions to military health and performance problems, with a view towards evaluating technical feasibility. Included are studies and investigations leading to candidate solutions that may involve use of animal models for testing in preparation for initial human testing. Research in this Program Element (PE) is designed to address the following: Areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of priority investments in science, technology, research, and development as stated the strategy and initiatives described in the Quadrennial Defense Review. Program development is peer-reviewed and fully coordinated with all Military Services, appropriate Defense Agencies or Activities, and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) funding. Research supported by this PE includes hemorrhage (bleeding) and resuscitation, diagnosis and treatment of brain injury,

treatments for extremity trauma (injury to tissue, head, face, jaw, and mouth, lungs, and burns), forward surgical intensive critical care, and en route care. Operational medicine efforts focus on injury prevention and reduction, psychological health and resilience, physiological health, and environmental health. Rehabilitation applied research focuses on neuromusculoskeletal injuries, pain management, regenerative medicine and sensory systems. Applied research efforts are also developing radiation medical countermeasures. And, within the area of military infectious diseases, applied researchers focus on wound infection prevention and antimicrobial countermeasures. As research efforts mature, the most promising efforts will transition to technology development (PE 0603115HP) or advanced concept development (PE 0604110HP) funding.

For the Army Medical Command, beginning in FY14, the military HIV research program funding is transferred from the Army to the Defense Health Program. Work in this area includes refining improved identification methods to determine genetic diversity of the virus, preclinical work in laboratory animals including non-human primates to identify candidates for global HIV-1 vaccine, and evaluating and preparing overseas sites for clinical trials with these vaccine candidates.

For the Army Medical Command, beginning in FY15, funding is provided to develop strategies to prevent, mitigate, and treat antibiotic resistant bacteria in wounds through the Combating Antimicrobial Resistant Bacteria - WRAIR Discovery and Wound Program.

The Army Medical Command also received DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury and Psychological Health Research. Because of the CSI annual structure, out-year funding is not programmed.

For the Air Force, this PE funds applied research which seeks to promote ‘omic’-informed personalized medicine, advanced diagnostic technologies and occupational toxicology with an emphasis on targeted prevention, diagnosis, and treatment. The delivery of pro-active, evidence-based, personalized medicine will improve health in Warfighters and beneficiaries by providing care that is specific to the situation and patient, to include preventing disease or injury, early and accurate diagnosis, and selection of appropriate and effective treatment. Personalized medicine will reduce morbidity, mortality, mission impact of illness/injury, and healthcare costs while increasing health and wellness of the AF population and efficiency of the healthcare system. This applied research supports multiple focus areas, each of which represents an identified barrier/gap which must be addressed for successful implementation of ‘omic-informed personalized medicine. Focus areas for applied research include knowledge generation research; ethical legal and social issues/policy research; bioinformatics research; educational research; research for development of advanced genomic diagnostic system. For efforts supported by this program element, research will be pursued with the intent to support solutions that answer Air Force specific needs. During this process, the efforts of other government agencies in those areas will be assessed to avoid redundancy.

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program					Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*			R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*		
B. Program Change Summary ($ in Millions)	**FY 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**
Previous President's Budget	46.761	47.898	55.101	-	55.101
Current President's Budget	59.968	73.201	58.251	-	58.251
Total Adjustments	13.207	25.303	3.150	-	3.150
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	15.000	25.303			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.793	-			
• Realignment in Support of the Global Health Security Agenda (GHSA) Initiative - Project 246A	-	-	3.150	-	3.150

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2014**	**FY 2015**
Project: 200A: *Congressional Special Interests*		
Congressional Add: *426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)*	15.000	-
Congressional Add: *469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	-	4.941
Congressional Add: *469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force)*	-	0.742
Congressional Add: *462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army)*	-	19.620
Congressional Add Subtotals for Project: 200A	15.000	25.303
Congressional Add Totals for all Projects	15.000	25.303

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0602115-Applied Biomedical Technology (-$1.793 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) Program (+$1.793 million).

FY 2014: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$15.000 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$25.303 million).

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0602115HP *I Applied Biomedical Technology*

FY2016: Realignment Global Health Security Agenda (GHSA) adjustment to DHP RDT&E, PE 0602115-Applied Biomedical Technology (+$3.150 million).

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 200A / *Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
200A: *Congressional Special Interests*	55.883	15.000	25.303	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

For FY14, DHP Congressional Special Interest (CSI) funding is directed to stimulate innovative research through a competitive, peer-reviewed research program focused on peer-reviewed traumatic brain injury and psychological health research. Because of the CSI annual structure, out-year funding is not programmed.

The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0602115 - Applied Biomedical Technology. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
Congressional Add: 426A – Traumatic Brain Injury and Psychological Health (TBI/PH) (Army)	15.000	-
FY 2014 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest program aimed to execute studies that inform the development of strategies to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, veterans, family members, caregivers, and communities. A key priority of the TBI/PH applied research program was to complement ongoing DoD efforts to ensure the health and readiness of our military forces by promoting a better standard of care for psychological health disorders and TBI in the areas of prevention, detection, diagnosis (identification of the nature and cause of an illness), treatment, and rehabilitation. Program announcements, programmatic reviews, Service-requested nominations, and ongoing studies that would benefit from program acceleration have been incorporated to address these priorities and gather proposals. In the area of TBI, researchers performed investigations to find a universally-agreed upon concussion grading system, and continued experiments into the effects of penetrating injuries on the brain and experiments on the effects of blasts on the brain. Proposals were solicited in the areas of blast-induced hyper-acceleration upon the generation of TBI and the role of inflammation in spreading TBI damage. Multiple awards relevant to combat casualty care were made including development of a large animal model of penetrating ballistic brain injury and development of metrics to define concussion and grade TBI. In the area of psychological health, researchers performed investigations to diagnose, prevent, and reduce symptoms of PTSD, and understand predictors of violence among workers in military settings.		
Congressional Add: 469A – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Army)	-	4.941

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 200A / *Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
FY 2014 Accomplishments: No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Applied Biomedical TechnologyProgram Element (PE) - 0602115.		
Congressional Add: 469B – CSI - Restore Core Applied Biomedical Technology (PE 0602115) (Air Force) ***FY 2014 Accomplishments:*** No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Applied Biomedical TechnologyProgram Element (PE) - 0602115.	-	0.742
Congressional Add: 462A – CSI - GDF Restore Core Applied Biomedical Technology (PE 0602115) (Army) ***FY 2014 Accomplishments:*** No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Applied Biomedical TechnologyProgram Element (PE) - 0602115.	-	19.620
Congressional Adds Subtotals	15.000	25.303

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

Individual efforts are monitored through a quarterly project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives), key performance parameters, and resolution of Force Health Protection gaps. Variances, deviations, and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of Science and Technology (S&T) governance. Annual reviews are also conducted in person for all of the projects within a specific program area.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 246A / *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
246A: *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*	-	-	-	3.150	-	3.150	3.157	2.552	1.949	1.949	Continuing	Continuing

A. Mission Description and Budget Item Justification

At the President's direction in late 2013, a National Strategy was created to address the critical issue of antimicrobial resistance. This strategy was devised using an interagency approach and ultimately approved at the executive level (2014). Inherent in this work are DoD sponsored efforts to support the DOD's beneficiaries, but that simultaneously complement national efforts to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria. One critical need identified is for new therapeutics, to include antibiotics. This effort's focus is on the development of new/novel antibiotics, especially one targeting the most resistant and worrisome Gram negative bacterial pathogens, using existing expertise at the Walter Reed Army Institute of Research (WRAIR), and leveraging other WRAIR capabilities to identify viable candidate targets for advanced discovery. This project supports (both directly and indirectly) Global Health Security Agenda priorities to respond rapidly and effectively to biological threats of international concern.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)	-	-	3.150

Description: Initiate an antibacterial (AB) drug discovery program directed toward military relevant drug-resistant bacteria that (a) encompasses assessment of external products/candidates/leads that may meet DoD requirements, (b) opens active intramural-based discovery efforts of new potential products/candidates/leads for development, and (c) initiates partnerships with external collaborators to develop/co-develop new potential AB treatment therapeutics.

FY 2014 Accomplishments:

No funding programmed. Targeted year of execution funding will be made available for this Global Health Security Agenda (GHSA) initiative.

FY 2015 Plans:

Funding will be made avilable in the year of execution (FY2015). First year of funding establishes the research program and initiates assessment of antibacterial programs from companies that have exited the commercial antibacterial drug discovery (direct contact and literature publications) market for potential leads; identifies and hire staff; develops desired therapeutic product profile criteria and DoD-focused Target Product Profiles to meet military requirements; identifies chemical hits/leads with development potential; performs assays to assess potential lead candidates; synthesizes key chemical compounds and newly designed lead optimization chemical compounds; begins to establish in vivo (living organism) model standards; identifies late stage potential

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 246A / *Combating Antibiotic Resistant Bacteria (CARB) - WRAIR Discovery and Wound Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
external programs that could potentially treat military relevant resistant bacteria; establishes agreements if intellectual property is involved; acquires 2-4 compounds and assesses for effectiveness in laboratory and/or animal models. ***FY 2016 Plans:*** Applied research efforts will continue to identify chemical compounds for assessment in the laboratory and testing in animals, and complete market analysis of external antibiotic programs to identify small molecules that are in early drug discovery (pre-clinical, 1-4 years away from advanced development) that may be expanded or elaborated. Will obtain rights if intellectual property is owned by existing companies or complete partner agreements in order to explore and co-develop new antibiotics leads, then conduct screening against military relevant strains and biofilms (microorganisms in which cells stick to each other on a surface) to select compounds for continued development.			
Accomplishments/Planned Programs Subtotals	-	-	3.150

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

An Acquisition Strategy will be developed to support future Milestone B when a clinical development candidate is identified and reaches TRL-6.

E. Performance Metrics

Performance metrics of the CARB drug discovery program will be provided through semi-annual status reports, periodic reviews by the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR) conducted by USAMRMC Decision Gate process. The performance metric benchmark is progression of research projects to Technology Readiness Level (TRL) 5 and their schedule to transition.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 306B / *Advanced Diagnostics & Therapeutics Research & Development (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
306B: *Advanced Diagnostics & Therapeutics Research & Development (AF)*	3.377	3.535	2.968	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Advanced Diagnostics & Therapeutics Clinical Translational Applied Research (Air Force): This project provides applied research funding needed to increase efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Modernization Thrust Areas to improve and enhance clinical Diagnosis, Identification, Quantification and Mitigation (DIQM) methods, techniques protocols, guidelines and practices for all DoD wounded, ill and/or injured beneficiaries.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Advanced Diagnostics & Therapeutics Research & Development (AF)	3.535	2.968	-

Description: This project provides applied research funding needed to perform research in the area of diagnostic assay development/refinement for diseases of operational significance. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and support research of evidence based therapeutics.

FY 2014 Accomplishments:

Continued to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Perform AF Surgeon General directed deep dive on Health as a National Strategic Imperative/Lifestyle Medicine. Continued review of nanotechnology research projects at the Massachusetts Institute of Technology as they relate to En-Route Care and Expeditionary Medicine missions. Transfer the leadership of the continuing forum to educate leaders on futures based thinking from AFMS/SG to OSD/HA. Continued support and development of Personalized Medicine/Genomic Medicine through specific outcome-based milestones for upcoming PC2 task assignment. Continue to leverage joint diagnostic efforts to meet AF mission requirements. Continue to analyze findings / outcomes of intramural project to identify and characterize epigenetic biomarkers of stress caused by high altitude conditions in a collaborative clinical translational research project in collaboration with the Uniformed Services University of the Healthcare Sciences (USUHS) to clinical practice / practice guidelines. Continue to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Perform AF Surgeon General directed deep dive on Health as a National Strategic Imperative/Lifestyle Medicine. Continued review of nanotechnology research projects at the Massachusetts Institute of Technology as they relate to En-Route Care and Expeditionary Medicine missions. Transfer the leadership of the continuing forum to educate leaders on futures based thinking from AFMS/SG to OSD/HA. Continued support and development of Personalized Medicine/Genomic Medicine through specific outcome-based milestones for upcoming PC2 task assignment. Continue to leverage joint diagnostic efforts to meet AF mission requirements. Continue to analyze findings /

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 306B / *Advanced Diagnostics & Therapeutics Research & Development (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
outcomes of intramural project to identify and characterize epigenetic biomarkers of stress caused by high altitude conditions in a collaborative clinical translational research project in collaboration with the Uniformed Services University of the Healthcare Sciences (USUHS) to clinical practice / practice guidelines. Began project evaluating Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) and Influenza A/H7N9 on the Biomeme smart-device based pathogen identification system to meet USAF requirements for infectious disease characterization. Initiated project to reduce the time to detection of the etiological agent(s) responsible for sepsis infection. Obtained IRB approval for analysis of the Chagas disease threat within high-risk military and civilian populations. Completed allelic discrimination of single nucleotide polymorphisms associated with metformin response in MHS patients with Type II Diabetes. ***FY 2015 Plans:*** Continue to support regenerative medicine program at Armed Forces Institute of Regenerative Medicine. Develop a process to effectively evaluate potential therapies/diagnostics/solutions to improve practices across the AFMS Complete AFMS Innovations nanotechnology research projects in collaboration with the Massachusetts Institute of Technology to address gaps in Hemorrhage control/hydration status, Pain management portable ultrasonography, and Compartment syndrome. Complete genomics clinical utility study. ***FY 2016 Plans:*** No Funding Programmed.			
Accomplishments/Planned Programs Subtotals	3.535	2.968	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc).

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
306C: *Core Adv Diagnostics & Epigenomics Applied Research (AF)*	-	-	-	1.728	-	1.728	1.757	1.987	2.025	2.066	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project provides applied research funding needed to perform research in the area of assay development/refinement for diseases of operational significance/ conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Core Adv Diagnostics & Epigenomics Applied Research (AF)	-	-	1.728
Description: This project provides applied research funding needed to perform research in the area of assay development/ refinement for diseases of operational significance/conditions. This will support increased efficiency and efficacy of care across the spectrum of Advanced Diagnostics and Therapeutics requirements in the defined Portfolio Areas. In addition, this project will support research for biosurveillance/occupational health activities and research/development of evidence based therapeutics ***FY 2014 Accomplishments:*** No funding programmed. ***FY 2015 Plans:*** No funding programmed. ***FY 2016 Plans:*** In support of personalized treatment for type 2 diabetes and cardiovascular disease, provide a predictive genetic therapeutic strategy based on pharmacogenetic therapies at the onset of diagnosis and aimed at delaying disease progression. Perform intramural project for the rapid identification of etiological pathogens of sepsis in support of same-day treatment-specific modalities. Leverage joint personalized medicine efforts to identify biomarkers of physiological response to opioid use. Transition smartphone-based pathogen identification system to meet Air Force requirements for personalized medicine and infectious disease characterization. Provide an analysis of the Chagas disease threat within high-risk military populations to determine if force health protection measures should be implemented to decrease exposure risk.			
Accomplishments/Planned Programs Subtotals	-	-	1.728

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 306C / *Core Adv Diagnostics & Epigenomics Applied Research (AF)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

Interagency Agreements and Interservice Support Agreements with the US Army, US Navy and the Department of Homeland Security are used to support ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 306D / *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
306D: *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*	-	-	-	1.728	-	1.728	1.758	1.988	2.026	2.066	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)	-	-	1.728
Description: This project supplies applied research funding needed to further develop approaches aimed at increasing the understanding of AF occupational and environmental hazards, advancing new concepts in developing methods of treatment in aeromedical care, and exploring new mechanisms to enhance human performance in critical Air Force occupations in the defined Modernization Thrust Areas to improve and enhance, maintain, preserve, and restore personnel performance, with the end goal of positively affecting personalized health and performance. ***FY 2014 Accomplishments:*** No funding programmed. ***FY 2015 Plans:*** No funding programmed. ***FY 2016 Plans:*** Begin to develop advanced diagnostics for brain effects from hypobaria in USAF high altitude ops. Develop mitigation approaches and therapeutics to counter effects from air transport and low-dose hypobaric exposures to the brain and traumatized organ systems. Develop passive dosimeters to support 24/7 exposure monitoring.			
Accomplishments/Planned Programs Subtotals	-	-	1.728

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 306D / *Core Occupational, Bioenvironmental, Aerospace Medicine & Toxicology Applied Research (AF)*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

ongoing scientific and technical efforts within this program -- these agreements are supplemented with Broad Area Announcement (BAA) and Intramural calls for proposal are used to award initiatives in this program and project following determinations of scientific and technical merit, validation of need, prioritization, selection and any necessary legal and/or regulatory approvals (IRB, etc)

E. Performance Metrics

Individual initiatives are measured through a quarterly annual project performance reporting system and program management review process -- performance is measured against standardized criteria for cost, schedule and performance (technical objectives) and key performance parameters. Variances, deviations and/or breaches in key areas are reviewed and a decision is rendered on any adjustments through a formalized process of S&T governance.***

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 372A / *GDF Applied Biomedical Technology*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
372A: *GDF Applied Biomedical Technology*	59.305	33.023	37.755	43.579	-	43.579	53.913	64.631	68.517	73.488	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - Applied Biomedical Technology: Applied biomedical technology research will focus on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development. Applied research will be conducted in the general categories of trauma, polytrauma (multiple traumatic injuries) and blast injury, rehabilitation, diagnosis and treatment of brain injury, radiation countermeasures, operational health and performance, physiological health, and psychological health and well-being for military personnel and families. Trauma, polytrauma and blast injury applied research focuses on control of bleeding, tissue viability (survival potential of a tissue or organ), diagnosis and life support, cranio-maxillofacial (head, neck, face, and jaw) injury, evacuation applications and practices, forward surgical applications, blast injury models and performance standards for protection systems, blast induced brain injury models, diagnostics and metrics for hearing loss and protection, blast exposure and breaching (process used to force open closed and/or locked doors), scar contracture (tightening of muscle, tendons, ligaments or skin that prevents normal movement), treatment of ocular and visual system traumatic injury, wound infection prevention and management, rapid screening of fresh whole blood, and antimicrobial (a substance that kills or inhibits the growth of microorganisms) countermeasures. Applied research in traumatic brain injury (TBI) focuses on diagnosis and treatment, disentanglement of combat stress injuries, and TBI in evaluations and clinical management. Operational medicine applied researchers also focus on injury prevention strategies for training and operational environments, sustainment of operational performance, early assessment and interventions to support Service member psychological and cognitive health, nutrition and dietary supplements, military, family and community psychological health and resilience, biomarkers of inhalation and other exposure to toxic substances, and military operational computational modeling. Applied research in radiation countermeasures includes activities to demonstrate capabilities to treat and mitigate the effects of acute radiation syndrome following radiation exposure.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: GDF Applied Biomedical Technology	33.023	37.755	43.579
Description: Applied Biomedical Technology Research focuses on refining concepts and ideas into potential solutions to military problems and conducting analyses of alternatives to select the best potential solution for further advanced technology development.			
FY 2014 Accomplishments: Military infectious disease research supported the development of the rapid Nucleic Acid Test screening of donor derived fresh whole blood in emergency settings for infectious diseases. Down selection of the Nucleic Acid Testing platform was moved to the right one year due to technical issues with industry partners and will be done in Q1FY15. Five projects were funded with the aim to develop antimicrobial countermeasures to combat multiple-drug resistant bacterial infections, and to identify and validate host and pathogen biomarkers to detect bacterial infections in wounds. Under acute respiratory diseases, continued support to maintain core competency (subject matter experts).			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Military operational medicine is grouped into four portfolios of injury prevention and reduction, psychological health and resilience, physiological health, and environmental health and protection. Injury prevention and reduction conducted applied research studies on blast injury models and performance standards for protections systems, blast exposure during breaching (process used to force open closed and/or locked doors), and diagnostics and metrics for hearing loss and protection. Psychological health and resilience focused on providing solutions that build service members, family and community resilience to sustain and restore psychological health and readiness, diagnosis of deployment-related psychological health problems, diagnosis of post-traumatic stress disorder (PTSD), military family and warfighter resilience, and suicide prevention. Physiological health conducted research on nutrition and dietary supplements, and the environmental health portfolio focused on pulmonary (pertaining to the lungs) health in the deployed environment, the incidence of pulmonary disease in returned warfighters, and warfighter performance and sustainment in extreme environments (such as extreme heat, cold, or altitude). Combat casualty care research supported multi-year studies, initiated in FY12 and FY13 with applied research being divided into portfolios for hemorrhage and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, and joint enroute care. Within the hemorrhage and resuscitation portfolio, a consortium of universities took a systems biology approach to studying the coagulopathy of trauma. Others efforts studied techniques for modulating inflammation. The neurotrauma research efforts studied mechanisms and treatments for TBI, distinguished between primary and tertiary blast injury, evaluated neurophysiologic and systematic changes during aero-medical evacuation and enroute care, investigated TBI in animals using advanced magnetic resonance imaging (MRI) and histopathology (microscopic examination of tissue) techniques, conducted a military relevant model of closed concussive head injury in longitudinal studies characterizing and validating single and repetitive mild TBI, and developed biomarkers in animals for progressive tau (human brain protein) pathology after TBI. The traumatic tissue injury research portfolio is starting pre-clinical trials in face restoration. Forward surgical/intensive critical care research started research to address pre-hospital care, emergency care, surgical care, intensive care, nursing care, advanced monitoring and battlefield medical equipment. Joint enroute care conducted studies to automate comprehensive clinical practice guidelines to improve enroute care of combat casualties, to access blood vessels in hemorrhagic (profuse bleeding) cases, and characterize human blood vessels in normal and low blood pressure trauma patients. Promising candidate products were evaluated for transition from applied research into technology development. Radiation health effects research pursued strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conducted animal studies in mice and non-human primates to characterize several compounds with the potential to mitigate or prevent Acute Radiation Syndrome resulting from lethal doses of radiation. Additional efforts identified targets for safe, effective, and FDA-approved prevention, mitigation or treatment of radiation injury, and increased understanding of the molecular mechanisms by which radiation injuries are initiated and cell cycling pathways triggered leading to multi-organ system dysfunction and death.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Clinical and rehabilitative medicine conducted studies in neuromusculoskeletal (system of nerves, muscles, and bones that enable movement) injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury that identified and evaluated candidate approaches for incorporation into restoration and rehabilitation strategies and medical products. Specific focus areas included: neuromusculoskeletal injury rehabilitation strategies and devices, prosthetics & orthotics (device/support that corrects/relieves an orthopedic problem), neural interfaces (invasive and non-invasive methods of using the brain for device control), the prevention of heterotopic ossification (growth of bone in abnormal places like soft tissue), and treatment of training injuries to the musculoskeletal system; novel therapeutics and devices for pain management; regenerative medicine-based approaches for limb (extremities) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury); and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. Clinical and rehabilitative medicine supported studies that started in FY13 and focused on evaluating and down-selecting novel diagnostic and treatment strategies in the areas of pain management and sensory system (vision, hearing, and balance) restoration and rehabilitation.			
FY 2015 Plans: Military infectious disease research is supporting multi-year studies in wound infection prevention and management and antimicrobial countermeasures; development of four novel FDA-approved therapeutics (e.g., drugs) to mitigate wound infection & biofilm processes, developing tools and practices for the detection/prevention of microbial infections in wounds and/or guide clinical wound management, performing confirmatory laboratory studies and initial animal studies to demonstrate drug potency and demonstrate biomarker accuracy and degree of confidence in identifying pathogens. Efforts to maintain core competency (subject matter expertise) in acute respiratory diseases and diagnostic systems for infectious diseases are continuing. Military operational medicine is grouped into four portfolios of injury prevention and reduction, psychological health, physiological health, and environmental health and performance. Injury prevention and reduction is establishing risk factors for heat injury susceptibility, establishing blast injury animal models for low-level repetitive blast exposure standards, and developing models of inner ear function to establish hearing injury criteria. Psychological health portfolio research is performing retrospective analysis of military workplace violence, examining reintegration difficulties following deployment, establishing an animal model for dependency and withdrawal associated with substance abuse, and establishing associations between deployment and psychological and physiological health problems. Physiological health is developing a reporting system for adverse events associated with dietary supplement use, and developing computational models that can predict bone and muscle health status. Environmental health and performance is studying select candidate biomarkers (biological indicators of health outcomes and disease) for inhalation exposure to toxic substances, and conducting dehydration studies to select stress biomarkers of hydration status.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Combat casualty care applied research is grouped into portfolios for hemorrhage (bleeding) and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, and joint enroute care. The hemorrhage and resuscitation research portfolio is supporting studies assessing the effectiveness of Valproic Acid, a FDA-approved anti-seizure drug, and ethinyl estradiol to increase survival of severe hemorrhage, establishing effects of modulating the inflammatory immune response associated with hemorrhagic shock and trauma. Neurotrauma research is developing traumatic brain injury (TBI) biomarkers (indicator of biological state or the past or present existence of a particular type of organism or molecule) and screening tools. The Traumatic tissue injury research portfolio is supporting treatments to address acute lung injury and to enhance healing of complex injuries of the face, extremities, groin and pelvis. Forward surgical intensive critical care is researching resuscitative interventions through seamless critical care. Enroute care, research aims to improve field management and safe air transport of patients with head and spine injuries. Radiation health effects research pursues strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Conduct animal studies in mice and non-human primates to address research data gaps and to characterize several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. The research aims to identify mechanisms of action, effectiveness, and safety in animal models in the development of therapeutics for ARS hematopoietic (bone marrow) sub-syndrome. Clinical and rehabilitative medicine research is conducting applied research in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing and sight) system traumatic injury. The neuromusculoskeletal injury portfolio is examining the impact of biopsychosocial effects on rehabilitation, improving the current technology available for residual limb-device interface, and developing objective metrics for device prescription and training. In pain management, research is studying enhanced chronic pain management using receptor antagonists (agents that block biochemical responses). Regenerative medicine research is studying novel tissue-engineered nerve grafts for currently unrepairable nerve injury, and treatment for re-innervated (restored nerve function) muscle. Sensory systems research is studying pre-clinical testing of sustained release drugs to prevent blinding complications following eye injury, and developing therapeutic drugs for hearing restoration after noise induced hearing loss. ***FY 2016 Plans:*** Military infectious diseases research will support multi-year studies in wound infection prevention and management and antimicrobial countermeasures, and will continue development efforts of four antibacterial projects and two projects for the detection of microbial infections in wounds. Studies will be aimed at development of novel therapeutics (drugs), biomarkers and clinical practice guidelines to mitigate wound infection and biofilm processes. Molecule(s) showing efficacy in laboratory studies			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
and initial animal studies, and/or biomarkers demonstrating accuracy in identifying pathogens will be further developed. Efforts to maintain core competency (subject matter expertise) in acute respiratory diseases will be continued. Military operational medicine is grouped into four portfolios of injury prevention and reduction, psychological health, physiological health, and environmental health and performance. Injury prevention and reduction will perform validation studies of risk factors for heat injury susceptibility, will validate blast injury animal models for low-level repetitive blast exposure standards, and will improve models of inner ear function to establish hearing injury criteria. Psychological health will conduct research to establish predictors of military workplace violence, will develop strategies for effective reintegration following deployment, and will continue establishing associations between deployment and psychological and physiological health problems to inform development of policies and guidelines. Physiological health will develop interventions for sustainable weight loss in military families, and will continue the development of computational models that can predict bone and muscle health status. Environmental health and protection portfolio research will refine candidate biomarkers (biological indicators of health outcomes and disease) for inhalation exposure to toxic substances and for stress response to mild and moderate dehydration in clinical populations. Combat casualty care applied research is divided into portfolios for hemorrhage (bleeding) and resuscitation, neurotrauma, traumatic tissue injury, forward surgical intensive critical care, and joint enroute care. Hemorrhage and resuscitation will identify new diagnostic tools and continue the development of treatments for abnormal hemorrhage following injury. Neurotrauma research will further develop traumatic brain injury (TBI) biomarkers and screening tools for far-forward medical evaluation of warriors. Forward surgical intensive critical care will study the effectiveness of acute lifesaving interventions in the pre-hospital/ hospital setting. Traumatic tissue injury researchers will study the mechanisms of acute lung injury, and research the use of lasers to prevent scar tissue formation. Enroute care will study the physiology of patient transport (effects of altitude, temperature on patients), and develop new non-invasive monitoring technologies. Radiation health effects research will continue strategies for protection, mitigation, and treatment of radiation-induced tissue injury due to high doses of radiation exposure. Will conduct animal studies in mice and non-human primates to address research data gaps and to characterize several compounds with potential to mitigate or prevent Acute Radiation Syndrome (ARS) resulting from lethal doses of radiation. Mitigators and therapeutics of ARS will focus primarily on bone marrow (hematopoietic), and to a lesser degree on gastrointestinal and pulmonary sub-syndromes. Based on research accomplishments, compounds will be evaluated as potential candidates for transition toward advanced development. Will identify mechanisms of action and demonstrate proof of principle for radioprotectants (prophylactics). Additional efforts will identify targets for safe, effective, and FDA-approved prevention, mitigation or treatment of radiation injury, and will increase understanding of the molecular mechanisms by which radiation injuries are initiated and cell cycling pathways triggered leading to multi-organ system dysfunction and death.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 372A / *GDF Applied Biomedical Technology*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Clinical and rehabilitative medicine research will pursue down-selection of candidate products for transition to technology development in the areas of neuromusculoskeletal injury, pain management, regenerative medicine, and/or sensory (hearing, sight and balance) system traumatic injury. Will conduct applied research in neuromusculoskeletal injuries to provide products and information solutions for diagnosis, treatment and rehabilitation after service-related injuries. Will study the effectiveness of leading solutions to alleviate acute and chronic battlefield pain, investigate solutions to replace or regenerate human cells, tissues, or organs to restore or establish normal tissue function, and conduct applied research to identify therapeutic targets to restore visual, auditory, and vestibular dysfunction associated with traumatic injury.			
Accomplishments/Planned Programs Subtotals	33.023	37.755	43.579

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Evaluate technical feasibility of potential solutions to military health issues. Implement models into data or knowledge and test in a laboratory environment. Milestone A packages will be developed to transition promising products to technology development funding.

E. Performance Metrics

Research is evaluated through in-progress reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports to include information on publications, intellectual property, additional funding support, and progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. The benchmark performance metric for transition of research conducted with applied research funding is the attainment of a maturity level that is at least Technology Readiness Level (TRL) 4, and typically TRL 5, or the equivalent for knowledge products. Products nearing attainment of TRL 5 will be considered for transition.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0602115HP / *Applied Biomedical Technology*	Project (Number/Name) 447A / *Military HIV Research Program (Army)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
447A: *Military HIV Research Program (Army)*	-	8.410	7.175	8.066	-	8.066	8.212	9.289	9.465	9.654	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project conducts research on the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS). Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for clinical trials with global vaccine candidates. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals. This project is jointly managed through an Interagency Agreement between US Army Medical Research Materiel Command (USAMRMC) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). This project contains no duplication of effort within the Military Departments or other government organizations. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas, and supports the principal area of Military Relevant Infectious Diseases to include HIV.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Military HIV Research Program	8.410	7.175	8.066
Description: This project conducts research on HIV, which causes AIDS. Work in this area includes refining improved identification methods to determine genetic diversity of the virus and evaluating and preparing overseas sites for future vaccine trials. Additional activities include refining candidate vaccines for preventing HIV and undertaking preclinical studies (studies required before testing in humans) to assess vaccine for potential to protect and/or manage the disease in infected individuals.			
FY 2014 Accomplishments: Program transitioned from the Army to DHP. Identified and characterized new populations who are at high risk of being infected with HIV for clinical evaluation of potential new vaccine candidates. Identified and develop new clinical trial sites at overseas locations to test and down-select best candidates for HIV vaccine. Initiated production of additional vaccines for various world-wide HIV subtypes and initiated pre-clinical evaluation in non-human primates. Identify and characterize new populations who are at high risk of being infected with HIV for clinical evaluation of potential new vaccine candidates. Identify and develop new clinical trial sites at overseas locations to test and down-select best candidates for HIV vaccine. Initiate production of additional vaccines for various world-wide HIV subtypes and initiate pre-clinical evaluation in non-human primates.			
FY 2015 Plans: Complete production of additional vaccine candidates for various world-wide subtypes. Develop improved methods to evaluate immune responses to selected HIV vaccine candidates in non-human primates. Analyze host genetic factors related to HIV			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0602115HP / *Applied Biomedical Technology*	**Project (Number/Name)** 447A / *Military HIV Research Program (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
acquisition and disease progression in acute HIV infection to inform vaccine development. Complete down-selection of best candidates for use in Phase 1 safety studies in human volunteers. ***FY 2016 Plans:*** Will continue to produce additional vaccine candidates for various world-wide subtypes. Will characterize these new sub-types and evaluate their capability to induce protective immune responses in non-human primates. Will down-select one or more vaccine candidates for use in safety studies in human volunteers.			
Accomplishments/Planned Programs Subtotals	8.410	7.175	8.066

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

The program receives periodic funding from Division of AIDS of NIAID ranging from $10-20 M/year through an Interagency Agreement with USAMRMC.

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance of the HIV research program is monitored and evaluated through an external peer review process, with periodic reviews by the HIV Program Steering Committee and the Military Infectious Diseases Research Program Integrating Integrated Product Team (IIPT) and in-process reviews (IPR) conducted via the USAMRMC Decision Gate process to include Defense Health Agency representation.